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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,211

10/30/2006

Bakulesh Mafatlal Khamar

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06/29/2011

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

06/29/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@burnslev.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/565,211	KHAMAR, BAKULESH MAFATLAL	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rodney P. Swartz	1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9 March 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-29, 32, 36-43 and 45-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-27, 36, 37 and 45-48 is/are rejected.
- 7) ☒ Claim(s) 28, 29, 32 and 38-43 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

**1. AFTER AN INTERNAL REVIEW, THE FOLLOWING NONFINAL OFFICE ACTION IS PUT FORTH.**

2. Applicant's Response to Office Action, received 9 March 2011, is acknowledged. Claims 22, 23, 32, 36, 38, 42, 45, 46 and 47 have been amended.
3. The Request under rule 48, filed 27 May 2008, is acknowledged and has been considered. Correction of Inventorship is in process.
4. Claims 22-29, 32, 36-43 and 45-48 are pending and under consideration.

### **Rejections Withdrawn**

5. The rejection of claim 22-27 and 32 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in light of the claim amendments.
6. The rejection of claim 45 under 35 U.S.C. 112, second paragraph, indefiniteness for whole cell being sonicate or extract, is withdrawn in light of the claim amendment.
7. The rejection of claims 46 and 47 under 35 U.S.C. 112, second paragraph, indefiniteness for dependence from a cancelled claim, is withdrawn.
8. The rejection of claims 28 and 29 under 35 U.S.C. 112, second paragraph, indefiniteness, for dependence from a cancelled claim, is withdrawn.

### **New Rejections**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1645

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 22-27 and 45-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Talwar et al (GB 2236480, 4 October 1991).

The claims are drawn to a method of treating, managing or preventing obstructive lung disease comprising administering to a patient a pharmaceutical composition comprising an effective amount of a medicament selected from the group consisting of: (a) heat killed whole cell *Mycobacterium w*, (b) sonicated *Mycobacterium w*, (c) a solvent extract of *Mycobacterium w*, wherein the solvent is selected from the group consisting of chloroform, ethanol, methanol, and acetone, (d) an enzymatic extraction of *Mycobacterium w*, wherein the enzyme is liticase, and (e) admixtures thereof.

Claim 47 is drawn to the method utilizing between  $10^8$  and  $10^9$  heat killed whole *Mycobacterium w*. Claim 48 is drawn to a method of treating, managing or preventing obstructive lung disease comprising administering to a patient a pharmaceutical composition comprising an effective amount of heat killed whole cell *Mycobacterium w*.

Talwar discloses a vaccine for the prophylactic and immunotherapeutic treatment of tuberculosis comprising a therapeutically effective amount ( $5 \times 10^8$ ) of *Mycobacterium w*. (see title, page 6, lines 9-15). Moreover, the patent discloses autoclaving the preparation, i.e., making the heat treated preparation (page 3, lines 22-24). Instant applicants also disclose the heat treatment as the terminal sterilization of the preparation, wherein autoclaving was indicated as the preferred final treatment of the instant invention. (paragraph 0070 and 0072 of the instant Application Publication US PGPUB US 2007/0059328 under the section "Example 2- The Process of Preparing a

Art Unit: 1645

Pharmaceutical Composition," page 4. Also, the patent discloses immunizing animals including mice and guinea pigs with  $10^7$  heat killed Mw subcutaneously and  $5 \times 10^8$  Mw SC, respectively, wherein these animals were challenged with *M. tuberculosis* 4 weeks after immunization. These animals were shown to have absence of tuberculosis in 80-85% of the animals, for instance (pages 4-7). Since the instant claims recite a method that entails preventing obstructive lung disease comprising administering to a patient, the teachings of Talwar anticipate the claimed invention as the patient populations are indistinguishable. Note that Talwar discloses a vaccine for preventing tuberculosis in patients and shows it works in animal models, and thus it can readily be envisaged that the vaccines will be administered to patients. By doing so, the vaccines will not only prevent the patients from tuberculosis but must also prevent from the obstructive lung disease, since the method taught by Talwar is the same as the instantly claimed invention.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talwar et al (GB 2236480, 4 October 1991).

Claims 36 and 37 depend from either claim 22 or claim 48, wherein the pharmaceutical composition further comprises an adjuvant. While Talwar is silent with

Art Unit: 1645

respect to an adjuvant, it would have been *prima facie* obvious to one of ordinary skill in the art to administer vaccine with an adjuvant as it is conventional, in the absence of evidence to the contrary.

### **Claim Objections**

11. Claim 28, 29, 32 and 38-43 are objected to because the claims depend from rejected claims.

### **Conclusion**

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday-Thursday from 7:30 AM to 6:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Gary Nickol, at (571)272-0835.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1645

/Rodney P Swartz/

Primary Examiner, Art Unit 1645

June 23, 2011